REMARKS

The Office Action of November 20, 2005 presents the examination of claims 6-12 as amended on September 13, 2005. The claims are not further amended in this paper.

Rejection over prior art

Claims 6-10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dunn, U.S. Patent 6,120,789 ("Dunn '789"). This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

In order to properly establish *prima facie* obviousness, the reference(s) relied upon by the Examiner must describe or suggest each feature of the invention as claimed. Also, the Examiner must explain some motivation, provided either by the cited reference(s) themselves, or by a problem known in the art, to modify the teachings of the reference(s) so as to obtain the present invention. *See, e.g. In re Dembiczak,* 50 USPQ2d 1614 (Fed. Cir. 1999). It is not sufficient that a modification can be made; there must be some explanation of why it should be made. *In re Fritch,* 23 USPQ2d 1780 (Fed. Cir. 1992).

Applicants submit that the Examiner fails to establish *prima facie* obviousness of the claimed invention. In particular, Dunn '789 fails to disclose or suggest at least one feature of the claimed invention, and the Examiner has not explained any motivation to modify the teachings of Dunn '789 to arrive at the claimed invention.

The present claim 6 includes the features that the formulation is cured and that the formulation comprises various particle combinations dispersed in a polymeric carrier. Claim 7 includes these same features and also recites that the formulation is shaped particularly.

On the other hand, Dunn '789 teaches a formulation that is administered in a liquid form and solidifies *in situ*. The composition is comprised of non-polymeric materials.

Thus, immediate distinction between the present invention and Dunn '789 is readily apparent in the carrier material from which the compositions are constructed, *i.e.* polymeric vs. non-polymeric materials.

Furthermore, the present claim 6 recites that various particle combinations are dispersed in the polymeric carrier. Among the particles are some of a carbonate and some that react with carbonate to release carbon dioxide.

During use of the present invention, a solidified composition is implanted. While resident in the body, bodily fluids infiltrate the composition and dissolve the carbonate and reacting substance, forming carbon dioxide that causes fine cracking within the formulation (*see,* page 5, lines 20-23 of the specification) or otherwise forces the insoluble or slightly soluble substance to the surface for dissolution or dispersal in the body.

On the other hand, Dunn '789 describes a formulation that comprises a "pore-forming" material that is insoluble in the formulation composition, but soluble in body fluids. The "pore forming material" described by Dunn '789 is either a solvent that leaches from the coagulating "matrix" forming channels and pores as it flows away or is a salt crystal that occupies space as the matrix forms, but then dissolves in body fluid present in the coagulating matrix, leaving a void. (See, col. 6, line 49 to col. 7, line 12.) There does not appear to be disclosure of use of carbonate to form a gas upon infiltration of the bodily fluid.

Thus, additional distinction between the present invention and Dunn '789 is apparent in the ingredients used to create "voids" in the composition.

Finally, there is also difference between the present invention and the composition disclosed by Dunn '789 in the way the inventions are used, which arise from the differences in the ingredients of the compositions. The composition of the instant invention is implanted in solid form *per se* ("cured")[1], whereas the composition of Dunn is administered in liquid form,

[1] The Examiner asserts that the feature of the present invention that it is a solid composition is not recited in the claims. However, Applicants submit that feature is indeed recited, as the polymer is described as "cured".

then coagulates to form a solid *in situ*. The Examiner points out disclosure in Dunn '789 however (col. 12, lines 53-55) that the formulation can be solidified outside the body and then administered. However, as to this embodiment, the Examiner should also consider that one of ordinary skill in the art would understand that such a composition should not contain any carbonate, unlike the presently claimed invention. *This is because carbonate present in the composition is added as a pore forming agent that is present to react with acid in the aqueous medium, resulting in foaming due to the generation of carbon dioxide to form the pores in the solid product.*

The Examiner also does not explain any motivation to modify Dunn '789 so as to achieve the present invention. In the use of a non-polymeric material for the composition and in stressing the advantage of applying the composition in liquid form (no incision is needed, the composition will fill a space tightly) Dunn '789 in fact expressly teaches away from the present invention.

For any one alone, or all together, of the above reasons, Applicants submit that the Examiner fails to establish *prima facie* obviousness of the invention as claimed in claims 6-10 over Dunn '789. Accordingly, the instant rejection cannot be sustained and must be withdrawn.

Claims 6-12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Dunn '789 in view of Fujioka, U.S. Patent 4,985,253 (Fujioka '253). This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Applicants again submit that the Examiner fails to establish *prima facie* obviousness of the claimed invention over the combined references. In the present instance, the combination of the secondary reference with the primary reference results in destroying of the operability of the invention of the primary reference. Such incompatibility in the teachings of the references precludes their use in combination to assert *prima facie* obviousness. *In re Gordon*, 221 USPQ 1125 (Fed. Cir. 1984).

As explained above, Dunn '789 teaches that the composition is applied in liquid form, and solidifies in the body. Alternatively, if the composition is solidified, it does not contain

carbonate. Furthermore, Dunn '789 requires that the composition be made from a non-polymeric material.

Fujioka '253 discloses a solid formulation made from a polymeric silicone material. The formulation of Fujioka '253 is administered as a cured solid. *See, e.g.* col. 4, line 40 to col. 5, line 25.

A formulation cannot be administered in both a liquid and a solid form. Furthermore, a composition cannot be made from only a non-polymeric material and include a cured polymeric material. Thus, combining Fujioka '253 with Dunn '789 results in inoperability of the invention disclosed by Dunn '789 and so this combination of references cannot be asserted to establish *prima facie* obviousness. Accordingly, the rejection of claims 6-12 under 35 U.S.C. § 103(a) as being unpatentable over Dunn '789 in view of Fujioka '253 is improper and must be withdrawn.

Finally, Applicants submit that the present invention achieves results that would not be expected by the artisan of ordinary skill who reads Dunn '789 and Fujioka '253. Dunn '789 teaches sodium carbonate as a pore forming agent only by virtue of its dissolving into the surrounding liquid, with formation of a pore by absence of the salt crystal. The various acids disclosed by Dunn '789; polyglycolide, poly-(DL)lactide, and stearic acid, are all mentioned in the context of carriers (col. 11, lines 7-64). Thus, Dunn '789 does not at all suggest the formation of carbon dioxide within the formulation and so does not appreciate the effect of such. Fujioka does not at all describe or suggest use of carbon dioxide-forming ingredients.

On the other hand, the present specification discloses, for example in Test Examples 1 and 2, that inclusion of carbon dioxide forming ingredients greatly enhances the release of insoluble or of slightly soluble substances from the formulation. This result must be deemed unexpected in view of the complete lack of appreciation of the effect of use of carbon dioxide-forming ingredients in the cited references.

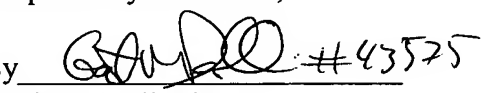
Applicants submit that the unexpected results shown in the specification are sufficient to rebut any case of *prima facie* obviousness of claims 6-12 that might be deemed to be established

by Dunn '789 in view of Fujioka '253 and so they provide yet another reason that the rejection of claims 6-12 as obvious over these references should be withdrawn.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell, Ph.D. (Reg. No. 36,623) at the telephone number below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Dated: March 30, 2006

Respectfully submitted,

By  #43575
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